

Remarks

Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66-70 are pending and under consideration in this application.

Claim 1, as amended, recites a method for isolating biological macromolecules with a filter comprising a first filter layer and a second filter layer within the same hollow body, support for which can be found in the original specification at least at paragraph [0041] (or paragraph [0056] of the published application), and in Figures 8a-b.

Claim 67, as amended, recites a method for isolating DNA molecules from cell lysates with a filter comprising a multilayered filter bed with at least a first filter layer and a second filter layer, support for which can be found in the original specification at least at paragraph [0041] (or paragraph [0056] of the published application).

Claim 69 has been amended to correct an obvious error.

New claim 71 recites a method for isolating biological macromolecules from cell lysates, the method comprising contacting a filtration apparatus assembled into a cartridge housing with the lysate, wherein the filtration apparatus comprises at least a first filter on top of a second filter, wherein the first and second filters are secured with an insert, and wherein the first filter is contacted with said lysate before said second filter. Support for this claim is found at least at paragraphs [0046], [0047] and in Figures 8a-b in the originally filed specification (paragraphs [0062], [0063] and Figure 8a-b of the published application).

No new matter is added by way of these claim amendments/ addition, and their entry is respectfully requested.

Interview Summary

In a telephone conference on October 14, 2008 between Examiner Sarae Bausch and Applicants' representative Daphne Reddy, the claimed invention and the outstanding rejections were discussed. Specifically, the schematic representations of the two filter layers in Figure 8A were discussed. The Examiner acknowledged that the two filter layers of Applicants' invention were present "within the same hollow body" and requested specific reference to such supportive language from the specification. The Examiner also pointed out to supportive language for the "multi-layered filter bed" in the specification. Applicants thank the Examiner for her time and helpful suggestions.

Claim Rejections Under 35 U.S.C. § 112, - New Matter

Claims 67-70 are rejected under 35 U.S.C. § 112, first paragraph as being non-compliant with the written description requirement. The Examiner states that the recitation of "wherein said filter comprises two layers directly contacting one another" is not adequately supported by the specification and raises new matter issues. The Examiner acknowledges that Figures 8a-8b describes a filtration apparatus with a first filter on top of a second filter (Page 3, Office Action).

Claim 67, as amended, recites a method for isolating DNA molecules from cell lysates with a filter comprising a multilayered filter bed with at least a first filter layer and a second filter layer, support for which can be found in the original specification at least at paragraph [0041] (or paragraph [0056] of the published application), and therefore is compliant with the written description requirement. Claims 68-70 dependent, directly or

indirectly, on amended claim 67 and therefore are also compliant with the written description requirement.

Applicants believe that this rejection under 35 U.S.C. § 112, 1st Paragraph is hereby moot, and respectfully request that the Examiner reconsider and withdraw this.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jones (PCT WO95/02049). Applicants respectfully traverse.

An anticipation rejection under 35 USC § 102 requires a showing that each limitation of a claim is found in a single reference, practice, or device. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). The test for anticipation is one of strict identity. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002). "Though anticipation is the epitome of obviousness, [they] are separate and distinct concepts" *See Jones v. Hardy*, 727 F.2d 1524, 1529, 220 USPQ 1021, 1025 (Fed. Cir. 1984).

The claimed invention

The claimed invention, as defined by claim 1, is directed to a method for the isolation of biological macromolecules, the method comprising contacting a filter with a biological sample comprising biological macromolecules, wherein the filter comprises a first filter layer and a second filter layer, wherein the first filter layer and the second filter layer are within the same hollow body and such that, the first filter layer contacts the biological macromolecules before the second filter layer, and wherein the first filter layer has a pore size smaller than the second filter layer. In the invention, the first filter layer comprises

pores of sufficient size to retard the flow of cellular debris and particles, and the second filter layer comprises pores of sufficient size to shear DNA molecules. The second filter does not bind the biological macromolecule. Moreover, the methods of the invention do NOT include an elution step.

Jones

Jones discloses a method for purifying target compounds such as nucleic acids from cells. The steps in this method involve: 1) lysis of cells, 2) applying lysate to a filter to remove cells and debris, 3) contacting filtered lysate with a solid phase matrix for nucleic acid binding, 4) separation of resultant filtered lysate, and 5) **elution of target compound from the matrix** (emphasis added- claim 1, WO 95/02049).

In particular, Jones teaches an apparatus comprising a first chamber to receive cell suspension, a filter downstream of the *first chamber* for retaining unlysed cells and cell debris, and *a second chamber* to receive filtrate downstream of the filter (page 8, paragraph 2, and Figure 5, WO 95/02049). Jones also teaches a plurality of reservoirs containing the appropriate reagents (page 9, paragraph 4, WO 95/02049).

That is, Jones does not teach or disclose that the filter and the solid phase matrix are housed within the “same” housing chamber or column. Jones also does not teach or disclose “multilayer filter beds” or “a filtration apparatus assembled into a cartridge housing”. In particular, the second matrix of Jones *binds* the target molecule and the methods *include an elution step*.

Arguments

The Examiner alleges that Jones teaches a method of separating biological compounds from cells by a filtration apparatus using two filters with increasing pore size in the direction of sample flow (Office Action, pages 5 & 6). The Examiner also alleges that Jones teaches the method of purifying nucleic acid from cells that comprises lysing a cell

suspension to form a cell lysate contacting nucleic acid and applying the cell lysate to filter to remove unwanted cells and cell debris.

Applicants submit that Jones' invention significantly differs from the instant invention. Jones does not teach or disclose that the filter and the solid phase matrix are housed within the "same" housing chamber or column. In fact, Jones clearly teaches a first and a second chamber that separately house the filter or filter matrix (Figure 5 and page 8, paragraph 2, WO 95/02049). Applicants particularly note that Jones passes the target molecule (e.g.: DNA) through the first filter, but NOT through the second filter. That is, Jones binds the target molecule to the second matrix (instead of passing it through like the instantly claimed invention) and it is further noted that the methods taught by Jones necessarily include an elution step (5).

Moreover, Jones does not teach or disclose "multilayer filter beds" or "a filtration apparatus assembled into a cartridge housing".

Therefore, all the claim elements claimed in the instant invention are not taught by Jones. Accordingly, Jones does not anticipate the present claims and Applicants therefore request that the rejection of claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66 under 35 U.S.C. § 102(b) be withdrawn.

2. Claims 67-70 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nieuwkerk *et al.* (Nieuwkerk). Applicants respectfully traverse.

The Examiner alleges that Nieuwkerk teaches stacked membranes that have a pore size of .1 to 12 microns and plasmid purification by contacting the filter with cell lysate.

Claim 67, as amended, recites a method for isolating DNA molecules from cell lysates with a filter comprising a multilayered filter bed with at least a first filter layer and a second filter layer, support for which can be found in the original specification at least at paragraph [0041].

While Nieuwkerk teaches stacked membranes, Nieuwkerk teaches separation of cell debris prior to filtration, *using centrifugation* (Nieuwkerk, Example I, lines 36-54) and not separation of cell debris using a filter.

Therefore, all the claim elements claimed in the instant invention are not taught by Nieuwkerk and it clearly does not anticipate the instant invention. Claims 68-70 dependent, directly or indirectly, on amended claim 67 and therefore are also not anticipated by Nieuwkerk.

Applicants believe that this rejection under 35 U.S.C. § 102(b) is hereby moot, and respectfully request that the Examiner reconsider and withdraw this.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,
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